

# EU Declaration of Conformity

Regulation (EU) 2016/425

## 1. This EU Declaration of conformity refers to the following products:

Product Name	Model	Classification/Type	Reference Number
Visitor Gown	ENM- 212	CAT III	212000001 212000002

## 2. Manufacturer's name and address is as below:

Company Name	En Ecza Deposu İlaç Medikal Özel Sağlık Hizmetleri İnşaat Taahhüt Ticaret A.Ş.
Address	Saray Mahallesi Gıdacılar Caddesi 3670 Ada 2 Parsel Kahramankazan ANKARA/ TURKEY
AB Authorized Representative	ENMED B.V.
Address	Oudeweg 109A 2031 CC Haarlem Amsterdam NETHERLANDS

## 3. The Conformity assessment according to the essential requirements has been done by Easespal according to

### EU Community Legislation

En Ecza Deposu İlaç Medikal Özel Sağlık Hizmetleri İnşaat Taahhüt Ticaret A.Ş. declares that under our sole responsibility that the product above to which this declaration relates are in conformity with the following standards or other regulatory laws following the provisions of PPE Directive EU 2016/425 Category III.

### Harmonised standart:

EN 14126: Protective clothing - Performance requirements and test methods for protective clothing against infective agents  
EN 13795: Surgical drapes, gowns and clean air suits, used as medical devices for patients, clinical staff and equipment - General requirements for manufacturers, processors and products, test methods, performance requirements and performance levels  
EN 13982-1: Protective clothing for use against solid particulates - Part 1: Performance requirements for chemical protective clothing providing protection to the full body against airborne solid particulates  
EN 13034:2005+A 1 :2009: Protective clothing against liquid chemicals - Performance requirements for chemical protective clothing offering limited protective performance against liquid chemicals  
EN 13688:2013: This International Standard specifies general performance requirements for ergonomics, innocuousness, size designation, ageing, compatibility and marking of protective clothing and the information to be supplied by the manufacturer with the protective clothing. This International Standard is only intended to be used in combination with other standards containing requirements for specific protective performance and not on a stand-alone basis.

### Declaration Type:

Self Declaration

### This declaration is valid until:

This certificate is initially issued on 17.05.2021 and will be valid for 5 years from the issue date.

### Place and Date of Issue:

Ankara / TURKEY

Date: 17.05.2021

### Company Sign:

EN ECZA DEPOSU İLAÇ MEDİKAL  
ÖZEL SAĞLIK HİZM. A.Ş.

EN ECZA DEPOSU İLAÇ MEDİKAL ÖZEL SAĞLIK HİZMETLERİ  
İNŞAAT TAAHHÜT TİCARET ANONİM ŞİRKETİ  
Adres Atakum Mah. 31010 Adana - Adana Adı No: 58 Merkezi MERSİN  
Adres No: 129430679 İstiklal V.D. : 3350707675  
MERSİS NO: 0335070767500001 T.C. SİCİL NO: 51525  
Tel: 0324 357 58 44 Fax: 0324 357 58 44

EN ECZA DEPOSU İLAÇ MEDİKAL ÖZEL SAĞLIK HİZMETLERİ  
İNŞAAT TAAHHÜT TİCARET A.Ş. SARAY MAH. GIDACILAR CAD.  
NO: 18 KAHRAMANKAZAN/ ANKARA  
VERGİ DAİRESİ: KAHRAMANKAZAN VERGİ NO:3350708675



## ENM-212 DISPOSABLE VISITOR GOWN



**Low lint.**  
**Latex free.**  
**Fluid repellent.**  
**Ultrasonically welded sleeve seams.**  
**Knitted cuffs for comfort.**

**ENM-212** is designed to protect from low hazard liquid spray. Visitor Gowns are designed to protect health professionals and patients from cross infection. These gowns have a barrier protection to fluids with the benefit of increased comfort.

### Specification

Material	:	Spunbond Non Woven	Cuff	:	Knitted Cuff
Fabric Weight	:	20 GSM			
Sewing	:	Lockstitch sewing for sleeves and shoulders. Overlock sewing for knitted cuff. Lockstitch for ribbon on the neck.			

# ENM-212 DISPOSABLE VISITOR GOWN

## Sizing

STANDART SIZE

## Comfort and Protection



CAT III

(EN 13688:2013)

EN 13034:2005+A1:2009

EN 14126:2003/AC:2004



DO NOT REUSE



DO NOT BLEACH



DO NOT IRON



CAUTION



FLAMMABLE  
KEEP AWAY FROM  
SPARKS OF  
FLAMES



CONSULT  
INSTRUCTIONS  
FOR USE



DO NOT WASH  
LAUNDERING  
IMPACTS UPON  
PROTECTIVE



DO NOT  
MACHINE DRY

## Storage and Disposal

- Store in dry, clean conditions in original packaging, away from direct sunlight, sources of high temperature, and solvent vapours
- Store within the temperature range -5°C to +45°C and with relative humidity below min %40 max80% Rh.
- Expected shelf life is five years from date of manufacture when stored as stated
- Replace garments if damaged, heavily contaminated or in accordance with local work practice or regulations
- Handle and dispose of contaminated garments with care and in accordance with applicable regulations.
- CE approved under Personal Protective Regulation (PPE) 2016/425, Category III

## Warnings and Limitations

Before use read and understand all user instructions and be sure that the product is suitable for the application and fitted correctly. Product must never be altered or modified. Prior to use inspect the clothing for any damage that could affect its protective function. Replace any damaged clothing. Care should be taken when removing contaminated garments, so as not to contaminate the user with any hazardous substances. If garments are contaminated, then decontamination procedures should be followed prior to removal of the garment. The wearing of chemical protective clothing may cause heat stress if appropriate consideration is not given to the workplace environment. Appropriate under garments should be considered to minimize heat stress or damage your garment.

### Do not use for:

Contact with heavy oils, sparks or flame, or combustible liquids; Environments with high mechanical risks (abrasions, tears, cuts); Environments with conditions of excessive heat.

# ENM-212 DISPOSABLE VISITOR GOWN

## Applications and Performance

<b>Non-Hazardous Particulates</b>	No
<b>Non-Hazardous Liquid Splash</b>	No
<b>Non-Hazardous Liquid Spray</b>	Yes
<b>Liquid Continuous</b>	No
<b>Contact/ Immersion</b>	No
<b>Gases and Vapours</b>	No
<b>Hazardous Dusts &amp; Fibres</b>	Nos
<b>Hazardous Liquid Splash</b>	No
<b>Hazardous Liquid Spray</b>	Yes, if chemical is compatible with suit material
<b>Acids/Alkalis</b>	No
<b>Organic Solvents</b>	No

## User Guide



**Attention**  
1. DO NOT reuse.

## Important Notice

This guide is only an outline. It should not be used as the only means for selecting protective clothing. Before using any protective clothing, the wearer must read and understand the user instructions for each product. Specific country legislation must be observed. If in doubt, contact a safety professional. Selection of the most appropriate PPE will depend on the particular situation and should only be made by a competent person knowledgeable of the actual working conditions and the limitations of PPE. Final determination as to the suitability of these products for a particular situation is the employer's responsibility. This information is subject to revision at any time. Always read and follow all User Instructions supplied with your Visitor Gown in order to ensure correct operation. If you have questions contact ENMED Technical Service.

**LIMITATION OF LIABILITY:** Except as provided above, ENMED shall not be liable or responsible for any loss or damage, whether direct, indirect, incidental, special or consequential arising out of the sale, use or misuse of ENMED products, or the user's inability to use such products.